

Basic Naturals™, LLC

5742 WEST HAROLD GATTY DRIVE
SALT LAKE CITY, UT 84116
Phone 801-517-7000 Fax 801-517-7003

December 29, 2004

Rec'd
JAN 11 2005

VIA: Certified Mail

Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

Re: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Stim-Free™. This notification is on behalf of Basic Naturals™, LLC.

Please review the information at your earliest convenience. Please contact me with any questions or if there is any further information I can provide regarding this matter.

Sincerely,

Heather Sprik
Heather Sprik
Legal Assistant

Enclosure

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**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93**

This notification is being filed on behalf of Basic Naturals™, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 W Harold Gatty Dr, Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Stim-Free™**.

The text of each structure-function statement for which notification is now being given is:

- | | |
|----------------|---|
| (Statement 1): | "Rapid Fat Loss" |
| (Statement 2): | "Produces Rapid Loss of Excess Body Fat." |
| (Statement 3): | "Produces Rapid Increase in Energy Levels." |
| (Statement 4): | "Clinically Proven Fat Burner." |
| (Statement 5): | "In an extraordinary, double-blind, placebo controlled clinical study, 20 overweight men and women were divided into three groups. Group A received the active Phosphosterine™ "Rapid Fat Loss Formula" complex, Group B received a placebo, and Group C acted to as a control (received nothing). Each group was instructed to follow a satisfying 1800 calorie meal plan and modest 3-day per week exercise program." |
| (Statement 6): | "Group A (the group taking the Stimulant-Free "Rapid Fat Loss Formula" Phosphosterine complex) experienced significant decrease in overall body weight. In fact, the loss of body weight was more than 8 times greater than the group who simply followed the diet and exercise program alone." |
| (Statement 7): | "Even more startling was the fact that the average loss of actual body fat in the Stimulant-Free Phosphosterine complex group was just short of ten pounds! That's a loss of actual body fat 62% greater than the placebo group and 63% greater than the control." |
| (Statement 8): | "The Stimulant-Free Phosphosterine complex group experienced a marked reduction in fatigue levels and felt 32% more energetic." |
| (Statement 9): | "Finally, there's a 100% stimulant-free, clinically proven way to lose excess pounds of deep spongy fat and flab." |

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Stim-Free™ – 180ct. Bottle
2	Stim-Free™ – 180ct. Bottle
3	Stim-Free™ – 180ct. Bottle
4	Stim-Free™ – 180ct. Bottle
5	Stim-Free™ – 180ct. Bottle
6	Stim-Free™ – 180ct. Bottle
7	Stim-Free™ – 180ct. Bottle
8	Stim-Free™ – 180ct. Bottle
9	Stim-Free™ – 180ct. Bottle

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Basic Naturals™, LLC	both
2	Basic Naturals™, LLC	both
3	Basic Naturals™, LLC	both
4	Basic Naturals™, LLC	both
5	Basic Naturals™, LLC	both
6	Basic Naturals™, LLC	both
7	Basic Naturals™, LLC	both
8	Basic Naturals™, LLC	both
9	Basic Naturals™, LLC	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Basic Naturals™, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that Basic Naturals™, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 27th day of December, 2004.

By: 

Daniel B. Mowrey, Ph.D.

Consultant to Basic Naturals™, LLC

Supplement Facts

Serving Size: 2 capsules
Servings Per Container: 90

	Amount Per Serving	% Daily Value†
Vitamin B3 (niacin)	20mg	100%
Phosphosterine™ a proprietary blend containing:	1331mg	
Calcium (as calcium phosphate)	73mg	7%
Commiphora mukul SE		†
Garcinia cambogia SE (HCA 125mg)		†
L-Tyrosine		†
Phosphorus (as mono & disodium, dipotassium & calcium phosphate)	119mg	12%
Potassium (as dipotassium phosphate)	67mg	2%
Sodium (as mono & disodium phosphate)	39mg	2%
Phosphatidylcholine		†
Scutellaria baicalensis (root) SE		†
Bupleurum chinense (root) SE		†
Epimedium brevicornum (herb) SE		†

†Percent Daily Values are based on a 2,000 calorie diet

† Daily Value not established

Other Ingredients: Rice Flour

Distributed by: **Customer Service Distribution Center**
Salt Lake City, UT 84116 • 1-800-898-5153

Fat Loss Components: Combination of Calcium, Phosphate, L-Tyrosine, Commiphora Mukul, Garcinia Cambogia and Phosphatidylcholine.

Protected by US Patent No. 6,113,949

This product is manufactured to be within all acceptable industry variances.

Standardized Extract (SE) means an extraction process providing the highest quality compound manufactured to acceptable industry variances.

Manufactured in the U.S.A.

www.BASICNATURALS.com

Directions: Take 2 capsules with a full glass of water three times a day as a dietary supplement. You may take Stim-Free™ with or without food. Do not exceed recommended serving.



STIM-FREE™

"STIMULANT-FREE" RAPID FAT LOSS*

In an extraordinary, double-blind, placebo controlled clinical study, 20 overweight men and women were divided into three groups. Group A received the active Phosphosterine™ "Rapid Fat Loss Formula" complex, Group B received a placebo, and Group C acted as a control (received nothing). Each group was instructed to follow a satisfying 1800 calorie meal plan and modest 3-day per week exercise program.*

After only 6 weeks, the verified results were astounding! Group A (the group taking the Stimulant-Free "Rapid Fat Loss Formula" Phosphosterine complex) experienced a significant decrease in overall body weight.* In fact, the loss of body weight was more than 8 times greater than the group who simply followed the diet and exercise program alone.*

Even more startling was the fact that the average loss of actual body fat in the Stimulant-Free Phosphosterine complex group was just short of 10 pounds! That's a loss of actual body fat 62% greater than the placebo group and 63% greater than the control.*

But there's more. The Stimulant-Free Phosphosterine complex group experienced a marked reduction in fatigue levels and felt 32% more energetic.*

What else does this scientifically validated clinical trial confirm? Simply this: Finally, there's a 100% stimulant-free, clinically proven way to lose excess pounds of deep spongy fat and flab.*



**OVERWEIGHT?
CAN'T TOLERATE STIMULANT-BASED
DIET PILLS?**

**TAKE THE STIM-FREE™
"RAPID FAT LOSS" QUIZ!**

- ☐ Do diet pills containing stimulants make you jittery, nervous or uncomfortable?
- ☐ Have you been looking for a stimulant-free, clinically proven, safe, fast and effective fat-loss product?
- ☐ Do you want to "jumpstart" your diet without "jumpstarting" central nervous system jitters?
- ☐ Do you want fast, visible results everyone will notice – without nervousness, dry mouth, or insomnia?
- ☐ Would you jump at a chance to get a product that produces rapid fat loss, increases energy, and makes you feel good without harsh stimulants?

**IF YOU ANSWERED "YES" TO ANY
ONE OF THESE QUESTIONS, THEN
STIM-FREE MAY BE THE PERFECT
FAT-LOSS FORMULA FOR YOU!**

Not for use by individuals under 18 years of age unless directed by a doctor. International distribution is not authorized without prior written consent. Product resale allowed only through authorized representatives.

Before starting this or any weight-control program, check with your health-care provider to make sure you are in overall good health. If your health-care provider has any questions, please have him or her call 1-800-898-5153.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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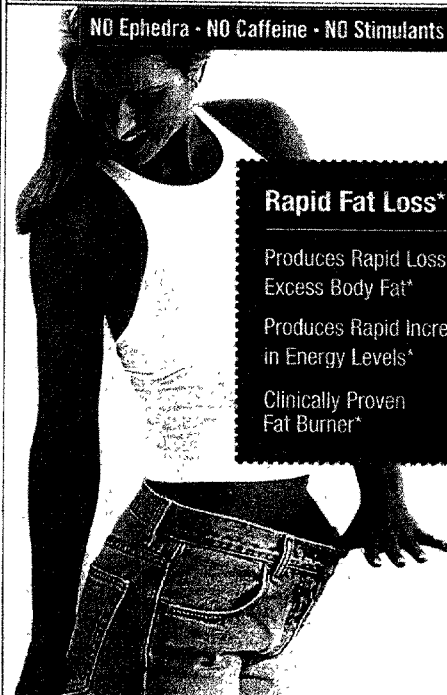


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STIM-FREE™

NO Ephedra • NO Caffeine • NO Stimulants



Rapid Fat Loss*

Produces Rapid Loss of
Excess Body Fat*

Produces Rapid Increase
in Energy Levels*

Clinically Proven
Fat Burner*

DIETARY SUPPLEMENT | 180 CAPSULES